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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/766,378 | 01/19/2001 | Peter R. Rhode | 48002-DIV (1758) | 8910 |

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| EXAMINER |
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VANDERVEGT, FRANCOIS P

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/766,378

Applicant(s)

RHODE ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 and 38-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29, 39, 40 and 44-49 is/are rejected.
- 7) ☒ Claim(s) 38 and 41-43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 08/960,190.

Claims 1-24, 30-37, 44 and 46 have been canceled.

Claims 25-29, 38-43, 45 and 47 are currently pending.

In view of Applicant's amendments filed August 5, 2005 and November 29, 2004 no outstanding grounds of rejection are maintained. The following represent NEW grounds of rejection and necessitate this Office Action being made NON-FINAL.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 26-29, 39, 40 and 44-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 5,869,270 to Rhode et al (of record). Although the conflicting claims are not identical, they are not patentably distinct from each other when "A represents at least one empty sc-MHC class II molecule" and "D represents at least one empty sc-MHC class II molecule" because claim 17 of the '270 patent is drawn to multimeric (or polyspecific) complexes of single chain MHC class II molecules. Claim 17 of the '270 patent, by way of its base claim, recites that the MHC class II molecule is composed of a class II beta chain and a class II alpha chain linked in sequence and does not recite that a peptide antigen is either attached or associated with the MHC molecule. Accordingly, the claim reads upon "empty" MHC molecules. While claim 17 of the '270 patent does not specifically recite "joining molecule," the claim is broadly drawn to read upon any multivalent MHC class II complex comprising two or more "linked" single chain MHC class II molecules, and the purpose of the joining molecules in the instant claims is to link the sc-MHC class II

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molecules. Accordingly; the instantly claimed polyspecific MHC complex when "A represents at least one empty sc-MHC class II molecule" and "D represents at least one empty sc-MHC class II molecule" constitutes an anticipatory species of the multivalent MHC complex of claim 17 of the '270 patent.

Claims 26, 29, 47 and 49 are included because the term "effector molecule" as broadly recited in the claims reads upon a second MHC class II molecule, as an MHC class II molecule "effects" an interaction between an APC and a helper T cell.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25-29, 39-40, 44-47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25-29, 39-40, 45, 47 and 49 are ambiguous and unclear in the recitation of "polyspecific MHC complex" because the term implies that the complex comprises more than 1 MHC molecule, giving the complex multiple specificities. However, in claims 25, 28, 45 and 48, when A is one empty sc-MHC class II molecule and C1, C2 and D are each independently "H" the complex comprises only a single MHC class II molecule of a single specificity and has no effector molecules. Accordingly, the claimed construct is not commensurate with the recitation of "polyspecific" in the claims. Similarly, in claims 26, 29, 47 and 49, when the formula is A-B-C or B-A-C and A is one MHC class II molecule and C is "H" the complex is monospecific.

Claims 44 and 46 are ambiguous and unclear in the recitation of "inhibitor." It is unclear from the claims and specification exactly what is being inhibited. For example, does the term refer to inhibitors of cellular processes, MHC class II/TCR interactions or peptide binding to MHC?

Appropriate clarification is required.

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Allowable Subject Matter


4. Claims 38 and 41-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. 
Patent Examiner
January 24, 2005


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
2/1/05